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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,708	06/16/2006	Stefan Bracht	RO4101US	5800

7590
D Peter Hochberg
6th Floor
1940 East 6th Street
Cleveland, OH 44114

10/20/2010

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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10/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,708	Applicant(s) BRACHT, STEFAN	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 11 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 10, 12-14 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 08/16/2010.

Claims 1-15 previously presented, and claims 16-20 are currently added.

Claims 1-20 are pending.

Response to Election/Restrictions

1. This application contains claims 1-4, 9, 10, 12-14 drawn to an invention nonelected with traverse in the reply filed on 03/15/2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-4, 9, 10, 12-14, 16-20 are included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim 17 recites "skin has chromatic vales", and applicants refers to paragraph [0048] for support, however this paragraph does not describe any chromatic values of the skin. Further the new claim 19 recites that "dyes and pigments is "incorporated in the backing", and applicants refer to paragraph [0022] for support, however, this paragraph teaches coating with the pigment, and not incorporation in general that is broader than coating.

If applicant contends there is support for this limitation, then applicant is requested to specify the page and line of said support. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 9, 10, 12-14, 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Degen (DE 10053375, translation currently provided) as evident by the provided articles: “4-aminobenzoic acid”, encyclopedia, “CINNAMIC ACID”, product identification, “Benzophenone”, IngredientsFeedbackScience, and “Lacquer definition”, Your Dictionary.

Degen discloses transparent transdermal therapeutic system (TTS) contain photosensitive active ingredient. The TTS comprises colorless active ingredients contained polymer matrix and has a backing layer. The matrix and the backing comprise UV absorbent that does not have pharmacological or therapeutic effect. UV absorbent homogeneously distributed as dissolved or dispersed form in the matrix and in the backing layer. Photosensitive active ingredient is nicotine. TTS has a transparent backing layer and a transparent active substance matrix therefore little noticeable during application to the skin. TTS provides protection of the photosensitive active ingredients against light decomposition. Transparent backing materials are preferably polyester, polyethylene, polypropylene, polyurethane, ethyl Vinyl acetate, or polyethylene terephthalate (PET), as those used by applicant. Matrix materials of the TTS are preferably polyacrylates, polyisobutylenes, polydimethylsiloxanes, or styrene-isoprene-block copolymers, as those used by applicant. Preferred UV absorber is present in amount of 5-10%, and present invention used 7.75% according to table 1. UV absorber includes p-aminobenzoic acid and its derivatives, cinnamic acid and its derivatives, and

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benzophenones. UV absorbers disclosed by the reference read on dyes or pigments since all of them have color (white) as evident by the provides articles: "4-aminobenzoic acid", encyclopedia; "CINNAMIC ACID", product identification; and "Benzophenone", IngredientsFeedbackScience. TTS can be multilayered. TTS applied to the skin and remains there for a long period, for example some hours to several days.

Regarding the claimed lightness color value claimed by claim 1 and chromatic values claimed by claim 17, such property is inherent to the patch disclosed by Degen being transparent and having the same structure and materials used by applicant. Further, regarding testing of the patch to determine the lightness color value and the method of testing as claimed by claim 16, these are not part of the claimed transdermal patch. It is only an in-vitro diagnostic test that is expected to provide the same results obtained from two similar transdermal delivery devices built from the same materials and tested under the same circumstances, and the recitation of this in-vitro test does not impart patentability to claims directed to transdermal device. The burden is on applicants to show that the claimed testing process resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Regarding coating of the dye or pigment on the backing layer as claimed by claim 4 using lacquer as claimed by claim 13, Degen discloses homogenous distribution or solvating the UV absorber in the backing material, and homogenous distribution will

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provide UV absorber on the surface of the backing forming coating. Lacquer is nothing but solvent, as evident by the definition provided from "Your Dictionary", and solvating the UV absorber in a solvent before application to the backing reads on lacquer claimed by claim 13.

Therefore, all the limitations of the rejected claims are met by Degen's reference.

Response to Arguments

6. Applicant's arguments filed 08/16/2010 have been fully considered but they are not persuasive.

Applicants argue that the UV absorbers taught by the reference only appear white when they are present as crystalline powder and they are not capable of coloring the transdermal therapeutic systems (TTS's) in which they are incorporated. Degen describes these UV absorbers as being "colourless substances" and the TTS is also described as being colourless (claims 1-5). The term "dye" relates to a substance which can be used to give colour to something (e.g., hair). The colourless UV absorbers described by Degen cannot be regarded as dyes since they cannot be used for dyeing. In turn, since the presently claimed patches differ from the patches disclosed by Degen with respect to structure/composition, the Examiner's conclusion that the claimed lightness color value would be inherent to Degen's patch is also incorrect.

In response to this argument, applicants' attention is directed to the scope of the present claims that are directed to a product, and all the elements of the product are taught by Degen's reference. The present claims are not directed to any specific dye or

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pigment, and claimed lightness color values L_1 are broad from 50 to 200% of L_2 , and L_2 is from 5° to 100°. The claims further recite “second or any other person” which encompasses almost any skin color. **Applicant admits that the UV absorbers taught by the reference are white in color**, and white is a color. Words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). In the present case, applicants did not define the terms “dye or pigment”.

The definition of Pigment” as defined by “Merriam Webster Dictionary” is as follows:

Definition of PIGMENT

“a substance that imparts black or white or a color to other materials.....”

<http://www.merriam-webster.com/dictionary/pigment?show=0&t=1287271404>

Therefore, pigment can be black or white and Degen teaches UV absorbers that are known to be white. Hence, the reference implies the presence of the white color in the matrix and backing layer as instantly claimed. Degen claims transparent patch including transparent reservoir and backing, and **preferably “colorless-transparent”**. This implies the presence of color, however, Degen preferred the colorless-transparent. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The presence of color is implied by Degen by teaching presence of UV absorber that are while in color.

As such, it is the examiner's position that the product advanced by Degen anticipates the compositions enumerated in the instant claim set. It has been held that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer. *See Atlas Powder versus Ireco*, 51 USPQ 2d 1943, (Fed. Cir. 1999).

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The fact that prior art taught away from the claim is, in fact, only a showing that prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency. The present claim is directed to product, which is identical to the product disclosed by the prior art and inherently will have the same properties and functions. It has been held that once a reference teaching product appearing to be substantially identical is made basis of rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to applicant to show an unobvious difference. The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same. The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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